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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/648,908      | 08/27/2003  | Scott J. Brabec      | P0009676.00         | 4394             |

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| EXAMINER |
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ALTER, ALYSSA MARGO

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| ART UNIT | PAPER NUMBER |
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3762

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09/22/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/648,908             | BRABEC ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Alyssa M. Alter        | 3762                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-10,12,14-25 and 27-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7-10,12,14-25 and 27-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____.                                     |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____.                         |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 3-5, 7-10, 12, 14-25 and 27-35 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

1. Claims 1, 4, 7, 12, 15, 23-25 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Mulier et al. (US 5,906,613). Mulier et al. discloses a lead with a ring electrode and a helical electrode, as seen in figure 10, which dispenses Ringer's solution, which is a saline solution, or another conductive solution.

As to claim 1, figure 10 depicts a lead with a proximal and distal end, a conductor 524 and an insulating sheath 500. The helical electrode 502 is the conductive structure and first electrode. Since the helical electrode dispensed Ringer's solution, the helix electrode is considered to be a closed cavity, in order to transport the fluid to the desired location. The distal end wall is the flat surface of the plastic cap 504 that faces the conductor 524. The plastic cap 504 as seen in figure 8 and 10 creates a closed cavity within the intermediate catheter tube 522. The insulative housing is the plastic cap 504 that circumscribes the second electrode, ring electrode 520, and has a port

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where the first electrode 502 is located. Also, since the Ringer's solution is dispensed from the helix, it is in intimate contact with the first electrode surface. In addition, the helix can have an insulated sheath as disclosed by Mulier et al. in col. 6, lines 11-16, thus creating an insulated helical fixation member.

Mulier et al. further discloses in col. 2, lines 12-30, that Ringer's solution can contribute to a wider affected area. Therefore an increase in affected area would reduce the current density since current density equals current flow divided by area (current density= current flow/area or  $J = I/A$ ). As such, the helical electrode produces a lower current density than the ring electrode.

As to claims 4 and 25, since the second electrode 520 protrudes from the plastic cap 504 and the plastic cap 504 has the port disposed within the center, the examiner considers the second electrode to protrude from the port.

As to claim 7, the conductive structure, connector 524, is proximate to the helical electrode 502.

As to claim 12, the straight portion of the helical electrode extending from the port of the plastic cap 504 to the onset of the helical coiled portion, is considered by the examiner to be the third uninsulated electrode surface.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 10, 14, 17-20, 22, 28-29 and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulier et al. (US 5,906,613) or in the alternative Mulier et al. (US 5,906,613) in view of Gates (US 5,408,744). Mulier et al. discloses the claimed invention but does not disclose expressly the conduction structure of the first electrode being greater or equal 10 mm<sup>2</sup>. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the conduction structure of the first electrode as taught by Mulier et al., with the range of greater or equal 10 mm<sup>2</sup>, because Applicant has not disclosed the range provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the conductive structure of the first electrode as taught by Mulier et al., since such a modification to the size of the electrode would be determined on an individual basis to meet specific patient needs.

Therefore, it would have been an obvious matter of design choice to modify conductive structure to obtain the invention as specified in the claim(s).

As to claims 14 and 29, Mulier et al. discloses the claimed invention but does not disclose expressly the conductive medium being a hydrogel. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify saline solution as taught by Mulier et al., with the hydrogel, because Applicant has not disclosed the specific compositions provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would

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have expected the Applicant's invention to perform equally well with the saline solution as taught by Mulier et al., because both mediums are in electrical contact with the electrodes, are disposed within the lead cavity and are capable of providing the predictable results of conducting electrical current.

Therefore, it would have been an obvious matter of design choice to modify conductive medium to obtain the invention as specified in the claim(s).

As to claims 17-20, 22 and 31-34, Mulier et al. discloses the claimed invention but does not disclose expressly the electrode surface composition. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the electrode surface as taught by Mulier et al., with the platinum black particles, iridium-oxide, ruthenium-oxide, titanium-nitride, because Applicant has not disclosed the specific compositions provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the electrode surface as taught by Mulier et al., because both electrodes are compatible with the human body and therefore, capable of being used within an implantable medical device, such as a lead.

Therefore, it would have been an obvious matter of design choice to modify electrode surface composition to obtain the invention as specified in the claim(s).

In the alternative, Mulier et al. discloses the claimed invention except for the electrode surface composition. Gates teaches that it is known to utilize platinum black, titanium, tantalum, iridium oxides and nitrides as set forth in column 7, lines 50-63. It would have been obvious to one having ordinary skill in the art at the time the invention

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was made to modify the electrode surface as taught by Mulier et al. with the electrode surface composition as taught by Gates, since it was known in the art that the compositions are all electrically conductive materials used for electrode surfaces and can therefore be altered to meet specific patient needs. In addition, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416 (See MPEP 2144.07)

As to claim 5, Mulier et al. discloses the claimed invention except for the second electrode that pierces the body tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the second electrode as taught by Mulier et al. with a second electrode to engage or pierce the body tissue since it was known in the art to employ electrodes that engage or pierce body tissue in order to provide the predictable results of ensuring proper dissemination of stimulation or treatment to the body.

2. Claims 3, 8 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulier et al. (US 5,906,613) in view of Peterfeso et al. (US 6,298,272). Mulier et al. discloses the claimed invention except for the stud joining the helix to the conductor and a retractable helix. Peterfeso et al. discloses the use of both fixed, non-retractable and retractable helix designs, as well as a stud joining a retractable helix to the conductor as seen in figure 3A as a stylet and reciprocal stylet slot 354 to be a stud that joins the conductor to the helical fixation member. Furthermore the helix is depicted as being flush with the distal end of the housing. It would have been obvious to one having

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ordinary skill in the art at the time the invention was made to have modified the helix design as taught by Mulier et al. with the retractable helix as taught by Peterfeso et al., since such a modification would provide the predictable results of enabling the physician to deliver the helix to the patient's tissue once the lead has reached its final destination and reduce the chances of accidentally engaging the patient's tissue during implantation.

3. Claims 21 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulier et al. (US 5,906,613) in view of Altman et al. (US 6,086,582). Mulier et al. discloses the claimed invention except for the steroid-loaded monolithic controlled release device (MCRD). Altman et al. teaches that it is known to dispense steroid-based drugs slowly through a lead, as disclosed in col. 3, lines 33-37. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the dispensed fluid as taught by Mulier et al. with the drug delivery means as taught by Altman et al, in order to provide the predictable results of modifying the treatment based on specific patients need and to facilitate localized drug delivery.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within



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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/  
Primary Examiner, Art Unit 3762

/Alyssa M Alter/  
Examiner  
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